## REMARKS

Claims 1-14 and 35-37 are pending. Claims 15-34 and 38-64 have been cancelled. Reconsideration and allowance are respectfully requested in light of the above amendments and following remarks.

***Rejections under 35 U.S.C. §112***

Claims 1, 2, 6, 7, 11, 12, 14, and 35-37 stand rejected under 35 U.S. C. §112, second paragraph, as assertedly being indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention. Insofar as they may be applied against the Claims, these rejections are respectfully traversed or overcome, as appropriate.

Regarding Claim 1, the Examiner stated that the metes and bounds of the claim were difficult to ascertain because the step of diagnosing an ailment does not correlate with the preamble. Frankly, this rejection does not make any sense to Applicant because Applicant is not aware of any requirement to correlate a claim limitation to the preamble. Moreover, the step to which Examiner is referring explicitly states "the ailment is related to the immunologic food sensitivity," which directly relates back to the term "immunological food sensitivity" referenced in the preamble. However, for the sake of comity, Applicant has amended the preamble. Accordingly, Applicant respectfully requests that the rejection of Claim 1 under 35 U.S.C. §112, second paragraph, be withdrawn.

Regarding Claim 2, the Examiner stated "a concentrating step is performed on the fecal matter sample to obtain a testing portion without further elaborating on exactly what steps are involved in a concentrating step." Applicant has amended Claim 2 to read "collecting a test

portion." Accordingly, Applicant respectfully requests that the rejection of Claim 2 under 35 U.S.C. §112, second paragraph, be withdrawn.

Regarding Claim 8, the Examiner stated that it was unclear how the supernatant portion of a centrifuged sample can be considered a concentrated sample. Applicant has amended Claim 8 to comport with the amendment to Claim 2; therefore, Applicant respectfully requests that the rejection of Claim 8 be withdrawn.

Regarding Claims 6 and 7, Claims 6 and 7 have been amended so that each item has the proper antecedent basis to overcome the rejections. Accordingly, Applicant respectfully requests that the rejections of Claims 6 and 7 under 35 U.S.C. §112, second paragraph, be withdrawn.

Regarding Claim 11, the Examiner stated "about equal" is unclear because Applicant does not specify the ELISA kit. Applicant would like to point the Examiner's attention to MPEP §2173.04, which reads (in part) as follows: "Breadth of a claim is not to be equated with indefiniteness." Additionally, Applicant would like to point the Examiner's attention to MPEP §2173.05(b)(A) with respect to Applicant's use of the term "about," which permits the use of the term "about." In particular, Applicant has drafted the claim to be used with whatever kit is chosen without regard to any one specific kit. Each ELISA kit requires an amount of diluted serum; therefore, the amount of the fecal sample should be "about equal" to the amount of diluted serum. Accordingly, Applicant respectfully requests that the rejection of Claim 11 under 35 U.S.C. §112, second paragraph, be withdrawn.

Regarding Claims 12 and 14, the Examiner states that freeze-drying and reconstituting does not constitute concentrating. Applicant has amended Claims 12 and 14 to comport with the amendment to Claim 2. Accordingly, Applicant respectfully requests that the rejections of Claims 12 and 14 under 35 U.S.C. §112, second paragraph, be withdrawn.

Regarding Claims 35-37, these claims had been previously amended to further narrow and limit the step of "diagnosing the ailment." Specifically, these claims recite the specific ailment(s) which are being diagnosed. Therefore, Applicant is clearly narrowing the scope of Claim 1 with Claims 35-37. Accordingly, Applicant respectfully requests that the rejections of Claims 35-37 under 35 U.S.C. §112, second paragraph, be withdrawn.

***Rejections under 35 U.S.C. §103(a)***

Claims 1-5, 8-10, 12-14, and 35-37 stand rejected under 35 U.S.C. §103(a) in view of "INTERNATIONAL ARCHIVES OF ALLERGY AND APPLIED IMMUNOLOGY," vol. 76, no. 2, 1985, pages 133-137, to Kolmannskog et al. ("Kolmannskog").

Specifically, Kolmannskog does not teach, suggest, or disclose a food sensitivity diagnosis based on fecal IgA concentrations. Kolmannskog only discloses total fecal IgA, not IgA specifically directed at a food antigen for which that food sensitivity would be diagnosed as the claimed invention does. In fact, Kolmannskog does not even mention a correlation between fecal IgA concentrations and immunological food sensitivities. The claimed invention, however, is directed toward an analysis of immunological food sensitivity correlated to IgA concentrations in the stool. Specifically, food allergies imply immediate physiological reactions to specific foods resulting in swelling, rashes, and so forth, which are characteristic of a very rapid and relatively violent immunological response. Immunological food sensitivities, on the other hand, are sensitivities mediated by T lymphocytes, which produce a delayed response resulting in IgA production. In other words, an immunological food sensitivity is an idiosyncratic reaction, which is relatively mild and has a slow response. Therefore, the claimed invention provides an analytical

tool to determine whether a patient has an immunological food sensitivity, which is often very difficult to otherwise determine, that Kolmannskog does not provide.

Moreover, each of the very different immunological reactions manifests itself with elevated concentrations of IgA, but, again, there is no correlation described in Kolmannskog. When a person has an allergic reaction (manifested by a violent and rapid immunological response that can place that person's life in immediate danger), Kolmannskog discloses an analytical technique for diagnosing ***food allergies*** through a measurement of IgA concentrations. Thus, Kolmannskog does not disclose the step of diagnosing or confirming an immunological food or drug ***sensitivity*** based on the fecal IgA concentrations.

Additionally, if a person has a food sensitivity (manifested by a slow and persistent immunological reaction), a person of ordinary skill in the art would not immediately analyze IgA concentrations, as shown by Kolmannskog. Additionally, because Kolmannskog does not teach, disclose, or suggest determining a food sensitivity based on fecal IgA concentrations, Kolmannskog cannot teach, suggest, or disclose determining an ailment based on the food sensitivity. Therefore, it is apparent one skilled in the art would not be able to perform the claimed invention until reviewing Applicant's disclosure and with hindsight.

Accordingly, Applicant respectfully requests that the rejections of Claims 1-5, 8-10, 12-14, and 35-37 under 35 U.S.C. §103(a) in view of Kolmannskog be withdrawn and that Claims 1-5, 8-10, 12-14, and 35-37 be allowed.

Claims 1-11 and 35-37 stand rejected under 35 U.S.C. §103(a) in view of "INCREASED CONCENTRATIONS OF FECAL ANTI-GLIADIN IgA ANTIBODIES IN UNTREATED CELIAC DISEASE," Clinical Chemistry. vol. 39, no. 4, 1993, pages 696-697, to Haas et al. ("Haas").

Specifically, Haas does not teach, suggest, or disclose the step of "diagnosing the immunologic food sensitivity based on the presence of the antibody." In fact, Haas simply states a correlation between fecal IgA concentrations and serum IgA concentrations for patients who had untreated and diagnosed celiac disease. Granted, a diagnosis cannot be made without such correlation, but the fact that Haas does not explicitly state a step of diagnosing illustrates that Haas did not take the further step of making an actual diagnosis based on fecal IgA concentrations. Moreover, Haas *teaches away from* the invention of using fecal IgA to make a diagnosis because Haas suggests in the last paragraph that a "*combined* assay of serum and fecal AGA IgA could prove to be more precise and thorough means of studying systematic and intestinal humeral immune responses in celiac disease." (Emphasis added.) In contrast, the claimed invention utilizes non-invasive techniques (namely, analyzing stool) to make diagnoses of ailments and food sensitivities, which clearly provides a benefit to which Haas does not. Accordingly, Applicant respectfully requests that the rejection of Claim 1 under 35 U.S.C. §103(a) in view of Haas be withdrawn and that Claim 1 be allowed.

Claims 2-11 and 35-37 depend on and further limit Claim 1. Hence, for at least the aforementioned reasons, these Claims would be deemed to be in condition for allowance.

***Double Patenting***

Claims 1-14 stand rejected under obviousness-type double patenting in view of Claims 1-13 of U.S. Patent No. 6,667,160 by Fine ("Fine"). Insofar as they may be applied against the Claims, these rejections have been overcome because Applicant has filed a terminal disclaimer in conjunction with this Response. Accordingly, Applicant respectfully requests that the rejections of Claims 1-14 under obviousness-type double patenting in view of Fine be withdrawn.

***Conclusion***

Applicant does not believe that any fees are due; however, in the event that any fees are due, the Commissioner is hereby authorized to charge any required fees due (other than issue fees), and to credit any overpayment made, in connection with the filing of this paper to Deposit Account 50-2180 of Storm LLP.

Should the Examiner require any further clarification to place this application in condition for allowance, the Examiner is invited to telephone the undersigned at the number listed below.

Respectfully submitted,

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